MALTA MEDICINES AUTHORITY

IN001-12 APPENDIX 2 VERSION 1

APPLICATION FOR A MANUFACTURER'S/IMPORTER'S LICENCE FOR MEDICINAL PRODUCTS AND/OR INVESTIGATIONAL MEDICINAL PRODUCTS FOR USE IN HUMANS

SECTION A: GENERAL INFORMATION

1 DETAILS OF PROPOSED LICENCE HOLDER

1.1 If Individual : Name _____

Surname _____

ID or passport number _____

1.2 If Company : Name _____

Company registration number _____

Legal and judicial representative of company:

Name _____

Surname _____

ID or passport number _____

2 LEGAL ADDRESS OF PROPOSED LICENCE HOLDER

Building Name/No. _____

Street _____

Locality _____

Postcode _____

If individual – address on ID card

If company – address registered with MBR

3 DETAILS OF PROPOSED LICENCE HOLDER CONTACT

3.1 Name _____

Surname _____

3.2 Address of Licence Holder Contact if different from Section 2

Building Name/No. _____

Street _____

Locality _____

Postcode _____

3.3 Telephone number _____

Mobile number _____

E-mail address _____

SECTION B: SITE INFORMATION

4 SITE DETAILS

4.1 Name of proposed manufacturer/importer

_____

4.2 Site Address of proposed manufacturer/importer

Building Name/No. _____

Street _____

Locality _____

Postcode _____

4.3 Site contact (if different from 3)

Name _____

Surname _____

Telephone number _____

Mobile number _____

E-mail address _____

4.4 Site Usage *[tick as appropriate]*

Indicate any other activities on this site which are not associated with medicinal products or investigational medicinal products:

☐ manufacture/importation/distribution/holding of medical devices

☐ manufacture/importation/distribution/holding of food supplements

☐ manufacture/importation/distribution/holding of veterinary medicinal products

☐ manufacture/importation/distribution/holding of cosmetic products

For sites with proposed importation activity, indicate if the site will be used:

☐ only for distribution (onward despatch of ready packed orders)

 for other purposes not indicated above. Please specify (e.g. order receipt; invoicing; order picking; handling of returned goods etc.)

_____

5 ACTIVITIES AT SITE

Tick the activities to be held at the site:

A. Manufacturing Operations of Medicinal Products

1 .1 Sterile products

1.1.1 *Aseptically prepared (processing operations for the following of dosage forms)*

- ☐ 1.1.1.1 Large volume liquids
- ☐ 1.1.1.2 Lyophilisates
- ☐ 1.1.1.3 Semi-solids
- ☐ 1.1.1.4 Small volume liquids
- ☐ 1.1.1.5 Solids and implants
- ☐ 1.1.1.6 Other aseptically prepared products (please specify):

1.1.2 *Terminally sterilised (processing operations for the following of dosage forms)*

- ☐ 1.1.2.1 Large volume liquids
- ☐ 1.1.2.2 Semi-solids
- ☐ 1.1.2.3 Small volume liquids
- ☐ 1.1.2.4 Solids and implants
- ☐ 1.1.2.5 Other terminally sterilised prepared products (please specify):

☐ 1.1.3 *Batch certification only*

1.2 Non-sterile products

1.2.1 *Non-sterile products (processing operations for the following dosage forms)*

- ☐ 1.2.1.1 Capsules, hard shell
- ☐ 1.2.1.2 Capsules, soft shell
- ☐ 1.2.1.3 Chewing gums
- ☐ 1.2.1.4 Impregnated matrices
- ☐ 1.2.1.5 Liquids for external use
- ☐ 1.2.1.6 Liquids for internal use
- ☐ 1.2.1.7 Medicinal gases
- ☐ 1.2.1.8 Other solid dosage forms
- ☐ 1.2.1.9 Pressurised preparations
- ☐ 1.2.1.10 Radionuclide generators
- ☐ 1.2.1.11 Semi-solids
- ☐ 1.2.1.12 Suppositories

- □ 1.2.1.13 Tablets
- □ 1.2.1.14 Transdermal patches
- □ 1.2.1.15 Intraruminal devices
- □ 1.2.1.16 Veterinary premixes
- □ 1.2.1.17 Other non-sterile medicinal product (please specify):

□ 1.2.2 *Batch certification only*

1.3 Biological medicinal products

1.3.1 *Biological medicinal products (list of product types)*

- □ 1.3.1.1 Blood Products
- □ 1.3.1.2 Immunological products
- □ 1.3.1.3 Cell therapy products
- □ 1.3.1.4 Gene therapy products
- □ 1.3.1.5 Biotechnology products
- □ 1.3.1.6 Human or animal extracted products
- □ 1.3.1.7 Tissue Engineered Products
- □ 1.3.1.8 Other biological medicinal products (please specify):

1.3.2 *Batch certification only (list of product types)*

- □ 1.3.2.1 Blood Products
- □ 1.3.2.2 Immunological products
- □ 1.3.2.3 Cell therapy products
- □ 1.3.2.4 Gene therapy products
- □ 1.3.2.5 Biotechnology products
- □ 1.3.2.6 Human or animal extracted products
- □ 1.3.2.7 Tissue Engineered products
- □ 1.3.2.8 Other biological medicinal products excluding blood products (please specify):

1.4 Other products or manufacturing activity

1.4.1 *Manufacture of:*

- □ 1.4.1.1 Herbal products
- □ 1.4.1.2 Homeopathic products

- □ 1.4.1.3 Other (please specify):

1.4.2 *Sterilisation of active substances/excipients/finished product:*

- □ 1.4.2.1 Filtration
- □ 1.4.2.2 Dry heat

- ☐ 1.4.2.3 Moist heat
- ☐ 1.4.2.4 Chemical
- ☐ 1.4.2.5 Gamma irradiation
- ☐ 1.4.2.6 Electron beam

☐ 1.4.3*Others(please specify):*

1.5 Packaging

1.5.1 *Primary packing*

- ☐ 1.5.1.1 Capsules, hard shell
- ☐ 1.5.1.2 Capsules, soft shell
- ☐ 1.5.1.3 Chewing gums
- ☐ 1.5.1.4 Impregnated matrices
- ☐ 1.5.1.5 Liquids for external use
- ☐ 1.5.1.6 Liquids for internal use
- ☐ 1.5.1.7 Medicinal gases
- ☐ 1.5.1.8 Other solid dosage forms (please specify):
- ☐ 1.5.1.9 Pressurised preparations
- ☐ 1.5.1.10 Radionuclide generators
- ☐ 1.5.1.11 Semi-solids
- ☐ 1.5.1.12 Suppositories
- ☐ 1.5.1.13 Tablets
- ☐ 1.5.1.14 Transdermal patches
- ☐ 1.5.1.15 Intraruminal devices
- ☐ 1.5.1.16 Veterinary products [this option is not available]
- ☐ 1.5.1.17 Other non-sterile medicinal products (please specify):

☐ 1.5.2 *Secondary packing*

1.6 Quality control testing

- ☐ 1.6.1Microbiological: sterility
- ☐ 1.6.2Microbiological: non-sterility
- ☐ 1.6.3Chemical/Physical
- ☐ 1.6.4Biological

Additional Comments:

B. Importation of Medicinal Products

2.1 Quality control testing of imported medicinal products

- ☐ 2.1.1 Microbiological : sterility
- ☐ 2.1.2 Microbiological: non-sterility
- ☐ 2.1.3 Chemical/Physical
- ☐ 2.1.4 Biological

2.2 Batch certification of imported medicinal products

2.2.1 *Sterile products*

- ☐ 2.2.1.1 Aseptically prepared
- ☐ 2.2.1.2 Terminally sterilised

☐ 2.2.2 *Non-sterile products*

2.2.3 *Biological medicinal products*

- ☐ 2.2.3.1 Blood Products
- ☐ 2.2.3.2 Immunological products
- ☐ 2.2.3.3 Cell therapy products
- ☐ 2.2.3.4 Gene therapy products
- ☐ 2.2.3.5 Biotechnology products
- ☐ 2.2.3.6 Human or animal extracted products
- ☐ 2.2.3.7 Tissue Engineered Products
- ☐ 2.2.3.8 Other biological medicinal products excluding blood products (please specify):

2.3 Other importation activities *(any other relevant importation activity that is not covered above e.g. importation of radiopharmaceuticals, medicinal gases, herbal or homeopathic products, etc.)*

- ☐ 2.3.1 Site of Physical importation
- ☐ 2.3.2 Importation of intermediate which undergoes further processing
- ☐ 2.3.3 Biological Active Substances
- ☐ 2.3.4 Other

Additional Comments:C. Manufacturing operations of Investigational Medicinal Products

1 .1 Sterile investigational medicinal products

1.1.1 *Aseptically prepared (list of dosage forms)*

- □ 1.1.1.1 Large volume liquids
- □ 1.1.1.2 Lyophilisates
- □ 1.1.1.3 Semi-solids
- □ 1.1.1.4 Small volume liquids
- □ 1.1.1.5 Solids and implants
- □ 1.1.1.6 Other aseptically prepared products (please specify):

1.1.2 *Terminally sterilised (list of dosage forms)*

- □ 1.1.2.1 Large volume liquids
- □ 1.1.2.2 Semi-solids
- □ 1.1.2.3 Small volume liquids
- □ 1.1.2.4 Solids and implants
- □ 1.1.2.5 Other terminally sterilised prepared products (please specify):

□ 1.1.3 *Batch certification only*

1.2 Non-sterile investigational medicinal products

1.2.1 *Non-sterile products (list of dosage forms)*

- □ 1.2.1.1 Capsules, hard shell
- □ 1.2.1.2 Capsules, soft shell
- □ 1.2.1.3 Chewing gums
- □ 1.2.1.4 Impregnated matrices
- □ 1.2.1.5 Liquids for external use
- □ 1.2.1.6 Liquids for internal use
- □ 1.2.1.7 Medicinal gases
- □ 1.2.1.8 Other solid dosage forms
- □ 1.2.1.9 Pressurised preparations
- □ 1.2.1.10 Radionuclide generators
- □ 1.2.1.11 Semi-solids
- □ 1.2.1.12 Suppositories
- □ 1.2.1.13 Tablets
- □ 1.2.1.14 Transdermal patches
- □ 1.2.1.15 Other non-sterile medicinal product (please specify):

□ 1.2.2 *Batch certification only*

1.3 Biological investigational medicinal products

1.3.1 *Biological medicinal products (list of product types)*

- □ 1.3.1.1 Blood Products
- □ 1.3.1.2 Immunological products
- □ 1.3.1.3 Cell therapy products
- □ 1.3.1.4 Gene therapy products
- □ 1.3.1.5 Biotechnology products
- □ 1.3.1.6 Human or animal extracted products
- □ 1.3.1.7 Tissue Engineered products
- □ 1.3.1.8 Other biological medicinal products excluding blood products (please specify):

1.3.2 Batch certification only *(list of product types)*

- □ 1.3.2.2 Blood Products
- □ 1.3.2.2 Immunological products
- □ 1.3.2.3 Cell therapy products
- □ 1.3.2.4 Gene therapy products
- □ 1.3.2.5 Biotechnology products
- □ 1.3.2.6 Human or animal extracted products
- □ 1.3.2.7 Tissue Engineered products
- □ 1.3.2.8 Other biological medicinal products excluding blood products (please specify):

1.4 Other investigational medicinal products or manufacturing activity

1.4.1 *Manufacture of:*

- □ 1.4.1.1 Herbal products
- □ 1.4.1.2 Homeopathic products
- □ 1.4.1.3 Other (please specify):

1.4.2 *Sterilisation of active substances/excipients/finished product:*

- □ 1.4.2.1 Filtration
- □ 1.4.2.2 Dry heat
- □ 1.4.2.3 Moist heat
- □ 1.4.2.4 Chemical
- □ 1.4.2.5 Gamma irradiation
- □ 1.4.2.6 Electron beam

□ 1.4.3 *Others* (please specify):

1.5 Packaging

1.5.1 *Primary packing*

- ☐ 1.5.1.1 Capsules, hard shell
- ☐ 1.5.1.2 Capsules, soft shell
- ☐ 1.5.1.3 Chewing gums
- ☐ 1.5.1.4 Impregnated matrices
- ☐ 1.5.1.5 Liquids for external use
- ☐ 1.5.1.6 Liquids for internal use
- ☐ 1.5.1.7 Medicinal gases
- ☐ 1.5.1.8 Other solid dosage forms
- ☐ 1.5.1.9 Pressurised preparations
- ☐ 1.5.1.10 Radionuclide generators
- ☐ 1.5.1.11 Semi-solids
- ☐ 1.5.1.12 Suppositories
- ☐ 1.5.1.13 Tablets
- ☐ 1.5.1.14 Transdermal patches
- ☐ 1.5.1.15 Other non-sterile medicinal products (please specify):

☐ 1.5.2 *Secondary packing*

1.6 Quality control testing

- ☐ 1.6.1 Microbiological: sterility
- ☐ 1.6.2 Microbiological: non-sterility
- ☐ 1.6.3 Chemical/Physical
- ☐ 1.6.4 Biological

Additional Comments:

D. Importation of Investigational Medicinal Products

2.1 Quality control testing of imported investigational medicinal products

- ☐ 2.1.1 Microbiological : sterility
- ☐ 2.1.2 Microbiological: non-sterility
- ☐ 2.1.3 Chemical/Physical
- ☐ 2.1.4 Biological

2.2 Batch certification of imported investigational medicinal products

2.2.1 *Sterile products*

- ☐ 2.2.1.1 Aseptically prepared
- ☐ 2.2.1.2 Terminally sterilised

☐ 2.2.2 *Non-sterile products*

2.2.3 *Biological products*

- ☐ 2.2.3.2 Immunological products
- ☐ 2.2.3.3 Cell therapy products
- ☐ 2.2.3.4 Gene therapy products
- ☐ 2.2.3.5 Biotechnology products
- ☐ 2.2.3.6 Human or animal extracted products
- ☐ 2.2.3.7 Other biological medicinal products excluding blood

2.3 Other importation activities *(any other relevant importation activity that is not covered above e.g. importation of radiopharmaceuticals, medicinal gases, herbal or homeopathic products, etc.)*

- ☐ 2.3.1 Site of Physical importation
- ☐ 2.3.2 Importation of intermediate which undergoes further processing
- ☐ 2.3.3 Biological Active Substances
- ☐ 2.3.4 Other

Additional comments:

6 **OTHER ACTIVE INGREDIENTS** produced or handled and appearing in the finished product.

[A] Potentially hazardous

Penicillins	☐ manufacture	☐ assembly
Cephalosporins	☐ manufacture	☐ assembly
Hormones	☐ manufacture	☐ assembly
Cytostatics/cytotoxics	☐ manufacture	☐ assembly

Others (please specify):

[B] Miscellaneous

Radioactive materials	☐ manufacture	☐ assembly
Homoeopathics	☐ manufacture	☐ assembly

7 INVESTIGATIONAL MEDICINAL PRODUCTS

If you propose to manufacture investigational medicinal products, indicate which of the following activities you intend to conduct:
(tick as appropriate)

- ☐ Bulk products will be purchased or otherwise sourced
- ☐ Intermediate products will be purchased or otherwise sourced
- ☐ Finished products will be purchased or otherwise sourced
- ☐ Blinding of investigational medicinal product

If none of the above have been ticked, please state who will be responsible for purchasing/sourcing (eg. Company Name/Sponsor):

_____

8 FOR PARTIAL MANUFACTURING ONLY

(Tick as appropriate)

8.1 OVER-PRINTING AND OVER-LABELLING

- ☐ Overprinting of primary packaging
- ☐ Overprinting of secondary packaging
- ☐ Over-labelling of primary packaging
- ☐ Over-labelling of secondary packaging

8.2 ASSEMBLY ACTIVITIES

- ☐ Replacement of secondary packaging
- ☐ Replacement of secondary packaging with change in blister quantity in each box
- ☐ Removal of leaflet
- ☐ Insertion of leaflet
- ☐ Removal/Insertion of other items. Please specify: _____

8.3 DOSAGE FORMS ASSEMBLED

- ☐ Liquid dosage forms
- ☐ Semi-solid dosage forms (including creams and ointments)
- ☐ Solid dosage forms including tablets and powders)
- ☐ Medical gases
- ☐ Other dosage forms. Please specify: _____

9 CONTRACT MANUFACTURE AND/OR ASSEMBLY

[tick if applicable]

☐ Licence holder/applicant is contract giver
(i.e. uses external manufacturers for some products)

List contract manufacturers/assemblers (as on contractor's license):

Name of proposed subcontractor (1):

_____

Site Address of proposed manufacturer/importer:

Building Name/No. _____

Street _____

Locality _____

Postcode _____

Country _____

[Fill in additional copies of this sheet if necessary]

10 CONTRACT QUALITY CONTROL TESTING (including testing for stability studies)

[tick if applicable]

☐ Licence holder/applicant is contract giver
(i.e. uses external test houses for some/all testing)

List contract laboratories (as on contractor's license/GMP certificate):

Name of proposed laboratory:

_____

Site Address of proposed laboratory:

Building Name/No. _____

Street _____

Locality _____

Postcode _____

Country _____

Testing activities at this site:

☐ Chemical/physical
☐ Microbiological/sterility/environmental/LAL
☐ Pyrogens (rabbit method)
☐ Bioassay
☐ Other (please specify: _____)

[Fill in additional copies of this sheet if necessary]

11 OTHER SPECIFIC PROCESSES/ACTIVITIES

(tick as applicable)

- ☐ Form/fill/seal processes
- ☐ Strip and/or blister packing
- ☐ Assembly of parallel-imported products
- ☐ Manufacture and/or assembly for export
- ☐ Sterilisation processes used (for products or components):
- ☐ Steam or steam/air
- ☐ Dry heat
- ☐ Irradiation/electron beam
- ☐ Biocidal gas/chemical

12 QUALIFIED PERSON

Please give the following details of the person who is to carry out the functions of Qualified Person (QP).

Name _____

Surname _____

Pharmacy Council QP Registration Number _____

Contact details:

Home telephone number _____

Office telephone number _____

Mobile number _____

E-mail address _____

Position held with the company other than QP if any:

_____

Type of employment with the company:

- ☐ Full time
- ☐ Part time
- ☐ Contract basis

Experience: Please state what experience you have had of the activities to be performed under the licence and how this has been acquired.

_____

_____

_____

I confirm that the above particulars are to the best of my knowledge and belief accurate and true.

Signed (proposed QP):
Date:

Signed (proposed Licence holder):
Date:

[Fill in additional copies of these two sheets if necessary]

13 PERSON RESPONSIBLE FOR PRODUCTION

Please give the following details for the person with overall responsibility for production.

Surname _____

Name _____

Qualifications

_____

_____

_____

Experience

_____

_____

_____

Name and function of the person(s) to whom he reports

_____

14 PERSON RESPONSIBLE FOR QUALITY CONTROL

Please give the following details of the person/s with overall responsibility for quality control.

Surname _____

Name _____

Qualifications

Experience

Name and function of the person(s) to whom he reports

[Fill in additional copies of this sheet if necessary]

15 STORAGE AND HANDLING OF MATERIALS

15.1 SITE NAME (if different from name of the licence applicant)

_____

15.2 SITE ADDRESS

_____

_____

_____

15.3 SITE CONTACT

Surname _____

Name _____

Telephone Number _____

Fax Number _____

15.4 SITE USAGE

Is this site used for distribution only ☐ Yes ☐ No
(i.e. onward dispatch of ready packed orders)
Or is this site used for other purposes ☐ Yes ☐ No

Please specify these other purposes (e.g. order receipt, invoicing, Assembly/picking of orders, handling of goods returned from customers).

[Fill in additional copies of these two sheets if necessary]

SECTION C: PROPOSED LICENSE HOLDER'S DECLARATION

I/We apply for the grant of a Manufacturer's/Importer's Licence to the proposed holder named in this application form in respect of the activities to which the application refers.

1. The licence to be subject to all the Standard Provisions applicable to Manufacturer's Licences under regulations for the time being in force under

2. The manufacturing operations are to be only in accordance with the information set out in the application or furnished in connection with it.

3. I/We declare that we hold the relevant product licences or are named on the relevant product licences as manufacturers and/or assemblers relating to the medicinal products we wish to manufacture and/or assemble pursuant to this application.

4. To the best of my knowledge and belief the particulars I have given in this form are correct and complete.

Signed : _____

Surname: _____

Name: _____

Date : _____

ANNEX 1: DOCUMENTS TO BE ATTACHED TO APPLICATION

A) Site Master File

B) Curriculum vitae of Production Manager

C) Curriculum vitae of Quality Control Manager

D) Certificate of Registration issued by MBR (for private & public companies only)

E) Planning Authority Permits for unlicensed sites listed on the application